

AMENDMENTS TO THE CLAIMS

1 (*Withdrawn*). A platelet concentrate unit comprising  
a sealed container,

a platelet concentrate mixture carried in the sealed container, the platelet concentrate mixture comprising a platelet concentrate volume, a plasma volume, and a synthetic platelet additive solution volume,

the platelet concentrate volume and the plasma volume having been collected from a unit of whole blood drawn from an individual donor and processed by centrifugation in a sterile, closed blood collection system which included the sealed container, and

the synthetic platelet additive solution volume having been mixed with the platelet concentrate volume and the plasma volume in the sterile, closed blood collection system, the synthetic platelet additive solution volume including ingredients that condition the platelet concentrate mixture for pathogen inactivation in the presence of a selected pathogen inactivating compound.

2 (*Withdrawn*). A platelet concentrate unit according to claim 1

wherein the sealed container includes an appendage sized and configured for coupling to tubing to transfer the platelet concentrate mixture from the sealed container to a selected destination.

3 (*Withdrawn*). A platelet concentrate unit according to claim 2

wherein the appendage couples to the tubing to form an essentially sterile connection.

4 (*Withdrawn*). A platelet concentrate unit according to claim 1

wherein the platelet concentrate volume is in a leukocyte-reduced condition as a result of filtration in the sterile, closed blood collection system.

5 (*Withdrawn*). A platelet concentrate unit according to claim 1

wherein the ingredients comprise an aqueous solution including sodium chloride, sodium citrate, sodium acetate, and sodium phosphate.

6 (*Withdrawn*). A platelet concentrate unit according to claim 1

wherein the selected pathogen inactivating compound is selected from a group comprising psoralens, methylene blue, dimethyl-methylene blue, riboflavin, or PEN 110, or combinations thereof.

7 (*Withdrawn*). A platelet pooling assembly comprising

a manifold sized and configured to convey multiple platelet concentrate mixtures from a plurality of platelet concentrate units as defined in claim 1, and

a container coupled to the manifold for pooling the multiple platelet concentrate mixtures.

8 (*Withdrawn*). A platelet pooling assembly according to claim 7

wherein the container includes an appendage sized and configured for coupling the container to a source of the selected pathogen inactivating compound.

9 (*Withdrawn*). A platelet pooling assembly according to claim 7

further including a filter for removing leukocytes from platelets.

10 (*Withdrawn*). A platelet pooling assembly comprising

a manifold sized and configured to convey multiple platelet concentrate mixtures from a plurality of a platelet concentrate units as defined in claim 1, and

a first container coupled to the manifold for pooling the multiple platelet concentrate mixtures, and

a second container coupled to the first container to receive the multiple platelet concentrate mixtures after centrifugation in the first container to remove residual red blood cells.

11 (*Withdrawn*). A platelet pooling assembly according to claim 10

wherein the second container includes an appendage sized and configured for coupling the second container to a source of the selected pathogen inactivating compound.

12 (*Withdrawn*). A platelet pooling assembly according to claim 10

further including a filter for removing leukocytes from platelets.

13 (*Withdrawn*). A platelet pooling assembly comprising

a first container for receiving a concentration of platelets, and

a second container integrally coupled by tubing to the first container to receive the concentration of platelets after centrifugation in the first container to remove residual red blood cells.

14 (*Withdrawn*). A platelet pooling assembly according to claim 13

wherein the first container includes a region of reduced volume to collect the residual red blood cells.

15 (*Withdrawn*). A platelet pooling assembly according to claim 13

wherein the first container includes a region of reduced volume to concentrate the residual red blood cells.

16 (*Withdrawn*). A platelet pooling assembly according to claim 13 further including a third container integrally coupled by tubing to the first container to receive the separated residual red blood cells.

17 (*Withdrawn*). A platelet pooling assembly according to claim 16 further including a one-way valve in the tubing between the first and third container to resist fluid flow from the third container toward the first container.

18 (*Withdrawn*). A platelet pooling assembly according to claim 13 wherein the tubing carries an in-line filter to remove leukocytes from platelets.

19 (*Withdrawn*). A platelet pooling assembly comprising a manifold sized and configured to receive multiple platelet concentrate units that have centrifugally separated from individual random donors, the manifold further including a site to receive a synthetic platelet additive solution for mixing with the multiple platelet concentrate units, and

a container coupled to the manifold for pooling a mixture of the multiple platelet concentrate units and the synthetic platelet additive solution.

20 (*Withdrawn*). A platelet pooling assembly according to claim 19 wherein the synthetic platelet additive solution volume includes ingredients that condition the multiple platelet concentrate units for pathogen inactivation in the presence of a selected pathogen inactivating compound.

21 (*Withdrawn*). A platelet pooling assembly according to claim 20 wherein the ingredients comprise an aqueous solution including sodium chloride, sodium citrate, sodium acetate, and sodium phosphate.

22 (*Withdrawn*). A platelet concentrate unit according to claim 20 wherein the selected pathogen inactivating compound is selected from a group comprising psoralens, methylene blue, dimethyl-methylene blue, riboflavin, or PEN 110, or combinations thereof.

23 (*Withdrawn*). A platelet pooling assembly according to claim 20 wherein the container includes an appendage sized and configured for coupling the container to a source of the selected pathogen inactivating compound.

24 (*Withdrawn*). A platelet pooling assembly according to claim 19 further including a filter for removing leukocytes from platelets.

25 (*Withdrawn*). A platelet pooling assembly according to claim 19 further including a second container coupled by tubing to the first container to receive the mixture after separation of residual red blood cells.

26 (*Withdrawn*). A platelet pooling assembly according to claim 25 further including a filter for removing leukocytes from platelets.

27 (*currently amended*): A manual blood collection system comprising a primary container sized and configured to hold a unit of whole blood drawn from an individual donor for centrifugal separation,

A<sup>2</sup> a platelet unit container sized and configured to hold a platelet concentrate and a first volume of plasma centrifugally separated from the unit of whole blood,

a plasma unit container sized and configured to hold a second volume of plasma centrifugally separated from the unit of whole blood,

~~an auxiliary container sized and configured to hold a synthetic platelet additive solution that, when mixed with the platelet concentrate and first volume of plasma, creates a platelet concentrate mixture, the synthetic platelet additive solution including ingredients that condition the platelet concentrate mixture for pathogen inactivation in the presence of a selected pathogen inactivating compound,~~

a synthetic platelet additive solution carried within the auxiliary container for mixing with the platelet concentrate and first volume of plasma to creates a platelet concentrate mixture,

the synthetic platelet additive solution comprising an aqueous solution comprising sodium chloride, sodium citrate, sodium acetate, and sodium phosphate for conditioning the platelet concentrate mixture for pathogen inactivation in the presence of a selected pathogen inactivating compound selected from a group comprising psoralens, methylene blue, dimethyl-methylene blue, riboflavin, or PEN 110, or combinations thereof, and

tubing integrally coupling the primary container, the platelet unit container, the plasma unit container, and the auxiliary container to form a sterile, closed blood processing system.

28 (*original*): A manual blood collection system according to claim 27 wherein, after processing in the sterile, closed blood processing system, the platelet concentrate mixture is held by the platelet unit container.

29 (*currently amended*): A manual blood collection system according to claim 28

wherein the platelet unit container ~~includes~~ comprises an appendage sized and configured for coupling coupled to transfer tubing to transfer the platelet concentrate mixture from the platelet unit container to a selected destination.

30(*original*): A manual blood collection system according to claim 29

wherein the appendage couples to the transfer tubing to form an essentially sterile connection.

31 (*Withdrawn*). A manual blood collection system according to claim 27

wherein, after processing in the sterile, closed blood processing system, the platelet concentrate mixture is held by the auxiliary container.

32 (*Withdrawn*). A manual blood collection system according to claim 31

wherein the auxiliary container includes an appendage sized and configured for coupling to transfer tubing to transfer the platelet concentrate mixture from the auxiliary container to a selected destination.

33 (*Withdrawn*). A manual blood collection system according to claim 32

wherein the appendage couples to the transfer tubing to form an essentially sterile connection

34(*original*): A manual blood collection system according to claim 27

wherein the tubing carries an in-line filter to remove leukocytes from platelets.

35(*cancelled*).

36(*cancelled*).

37 (*Withdrawn*). A manual blood collection system according to claim 27

further including a red blood cell unit container sized and configured to hold red blood cells centrifugally separated from the unit of whole blood, and

wherein the tubing integrally couples the primary container, the platelet unit container, the plasma unit container, the red blood cell unit container, and the auxiliary container to form a sterile, closed blood processing system.

38 (*Withdrawn*). A manual blood collection system according to claim 37

wherein the plasma unit container carries an additive solution for mixing with red blood cells.

39 (*Withdrawn*). A manual blood collection system according to claim 37

further including a container holding a synthetic red blood cell additive solution including ingredients that condition the red blood cells for pathogen inactivation in the presence of a selected pathogen inactivating compound.

40 (*Withdrawn*). A manual blood collection system according to claim 39 wherein the ingredients include sodium citrate, sodium phosphate, adenine, and mannitol.

41 (*Withdrawn*). A manual blood collection system according to claim 39 wherein the ingredients further include dextrose.

42 (*Withdrawn*). A manual blood collection system according to claim 37 wherein the tubing carries an in-line filter to remove leukocytes from red blood cells.

43 (*Withdrawn*). A system for collecting a pooled therapeutic platelet unit conditioned for pathogen inactivation from random donor platelet units comprising

means for collecting from a unit of whole blood drawn from an individual donor and processed by centrifugation in a sterile, closed blood collection system, a random donor sterile platelet component unit that has been conditioned for pathogen inactivation by the mixing, in the sterile, closed blood processing system, of a prescribed platelet additive solution, and

means for pooling in a sterile, closed system a plurality of random donor sterile platelet component units to provide a pooled random donor sterile platelet component dose that is conditioned for pathogen inactivation due to the presence of the platelet additive solution.

44 (*Withdrawn*). A system according to claim 43

further including means for subjecting the pooled random donor sterile platelet component dose to closed system leukocyte filtration.

45 (*Withdrawn*). A system according to claim 43

further including means for subjecting the random donor sterile platelet component unit to closed system leukocyte filtration.

46 (*Withdrawn*). A system according to claim 43

further including means for mixing with the pooled random donor sterile platelet component dose a desired volume of a pathogen inactivating compound to provide a treatment-ready pooled random donor dose.

47 (*Withdrawn*). A system according to claim 46

further including means for subjecting the treatment-ready pooled random donor dose to pathogen decontamination.

48 (*Withdrawn*). A system for collecting a pooled therapeutic platelet unit conditioned for pathogen inactivation from random donor platelet units comprising

means for collecting from a unit of whole blood drawn from an individual donor and processed by centrifugation in a sterile, closed blood collection system, a random donor sterile platelet component unit, and

means for pooling in a sterile, closed system a plurality of random donor sterile platelet component units, while also mixing, in the sterile, closed system, a prescribed platelet additive solution, to provide a pooled random donor sterile platelet component dose that is conditioned for pathogen inactivation due to the presence of the platelet additive solution.

49 (*Withdrawn*). A system according to claim 48

further including means for subjecting the pooled random donor sterile platelet component dose to closed system leukocyte filtration.

50 (*Withdrawn*). A system according to claim 48

further including means for subjecting the random donor sterile platelet component unit to closed system leukocyte filtration.

51 (*Withdrawn*). A system according to claim 48

further including means for mixing with the pooled random donor sterile platelet component dose a desired volume of a pathogen inactivating compound to provide a treatment-ready pooled random donor dose.

52 (*Withdrawn*). A system according to claim 51

further including means for subjecting the treatment-ready pooled random donor dose to pathogen decontamination.

53 (*Withdrawn*). A method for collecting a random donor platelet unit conditioned for pathogen inactivation comprising the step of collecting from a unit of whole blood drawn from an individual donor and processed by centrifugation in a sterile, closed blood collection system, a random donor sterile platelet component unit that has been conditioned for pathogen inactivation by the mixing, in the sterile, closed blood processing system, of a prescribed platelet additive solution.

54 (*Withdrawn*). A method according to claim 53

further including the step of subjecting the random donor sterile platelet component unit to closed system leukocyte filtration.

55 (*Withdrawn*). A method according to claim 53

further including the step of collecting from the unit of whole blood in the sterile, closed blood processing system, at least one additional blood component.

56 (*Withdrawn*). A method for collecting a pooled therapeutic platelet unit conditioned for pathogen inactivation from random donor platelet units comprising the steps of

collecting from a unit of whole blood drawn from an individual donor and processed by centrifugation in a sterile, closed blood collection system, a random donor sterile platelet component unit that has been conditioned for pathogen inactivation by the mixing, in the sterile, closed blood processing system, of a prescribed platelet additive solution, and

pooling in a sterile, closed system a plurality of random donor sterile platelet component units to provide a pooled random donor sterile platelet component dose that is conditioned for pathogen inactivation due to the presence of the platelet additive solution.

57 (*Withdrawn*). A method according to claim 56

further including the step of subjecting the pooled random donor sterile platelet component dose to closed system leukocyte filtration.

58 (*Withdrawn*). A method according to claim 56

further including the step of subjecting the random donor sterile platelet component unit to closed system leukocyte filtration.

59 (*Withdrawn*). A method according to claim 56

further including the step of mixing with the pooled random donor sterile platelet component dose a desired volume of a pathogen inactivating compound to provide a treatment-ready pooled random donor dose.

60 (*Withdrawn*). A method according to claim 59

further including the step of subjecting the treatment-ready pooled random donor dose to pathogen decontamination.

61 (*Withdrawn*). A method for collecting a pooled therapeutic platelet unit conditioned for pathogen inactivation from random donor platelet units comprising the steps of

collecting from a unit of whole blood drawn from an individual donor and processed by centrifugation in a sterile, closed blood collection system, a random donor sterile platelet component unit, and



pooling in a sterile, closed system a plurality of random donor sterile platelet component units, while also mixing, in the sterile, closed system, a prescribed platelet additive solution, to provide a pooled random donor sterile platelet component dose that is conditioned for pathogen inactivation due to the presence of the platelet additive solution.

62 (*Withdrawn*). A method according to claim 61

further including the step of subjecting the pooled random donor sterile platelet component dose to closed system leukocyte filtration.

63 (*Withdrawn*). A method according to claim 61

further including the step of subjecting the random donor sterile platelet component unit to closed system leukocyte filtration.

64 (*Withdrawn*). A method according to claim 61

further including the step of mixing with the pooled random donor sterile platelet component dose a desired volume of a pathogen inactivating compound to provide a treatment-ready pooled random donor dose.

65 (*Withdrawn*). A method according to claim 64

further including the step of subjecting the treatment-ready pooled random donor dose to pathogen decontamination.

---